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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,572	04/19/2004	Lowell L. Wood JR.	SE1-0034-US	3210

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EXAMINER
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CAMPBELL, VICTORIA P

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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06/23/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/827,572	<b>Applicant(s)</b> WOOD, LOWELL L.	
	<b>Examiner</b> VICTORIA P. CAMPBELL	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 35-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/22/08 6/27/08  
10/13/08 12/30/08 1/23/09 2/27/09 5/14/09.

### **DETAILED ACTION**

This is the second Office Action based on the 10/827572 application filed April 19, 2004.

Claims 1-34 as presented are currently pending and considered below.

#### ***Priority***

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: Applicant has not properly claimed priority to any application listed at the beginning of the specification.

#### ***Drawings***

2. The drawings are objected to because the drawings are generally informal and somewhat difficult to read and/or interpret. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be

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necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Terminal Disclaimer***

4. The terminal disclaimers filed on March 26, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Applications 10/827,576 and 10/827,390 have been reviewed and are NOT accepted.

5. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-8, 17, 20, 21, 25-30, and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by USPGPub 2002/0065509 A1 to Lebel et al.

Regarding the above claims, Lebel et al disclose a device comprising a body portion (6); at least one extensible finger (16) coupled to said body portion; at least one reservoir (84) in communication with said extensible finger; and a control circuitry (Paragraph [0140]) coupled to said body portion. Lebel et al further disclose a device for data storage [0139], a sensor [0152], a pump or actuator (86; [0140]), a wireless data transmitter and receiver or controller ([0141]-[0148]), and a source of a drug [0139]. Lebel et al further disclose a device for shunting flow (16), and a fluid dispenser carried by the extensible finger (terminal end of catheter 16) to operate at a controlled rate [0160]. Lebel et al also disclose a processor (72), software [0148], that the device is configured for full placement in vivo, in a human animal, in a location corresponding to one physiological variable that needs to be treated (Abstract). Furthermore, Lebel et al disclose that the device provides a treatment to the patient comprising a medical agent (insulin delivery), and that the device communicates exterior to the patient (Fig. 3).

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8. Claims 1-8, 17, 20, 21, 25-30, and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by USPN 4,944,659 to Labbe et al.

Regarding the above claims, Labbe et al disclose a device comprising a body portion (3); at least one extensible finger (20) coupled to said body portion; at least one reservoir (12) in communication with said extensible finger; and a control circuitry (Figure 4) coupled to said body portion. Labbe et al further disclose a device for data storage (Fig. 4), a sensor (70; Col. 4, lines 11-16), a pump or actuator (52), a wireless data transmitter and receiver or controller (60), and a source of a drug (Col. 4, lines 24-25). Labbe et al further disclose a device for shunting flow (20), and a fluid dispenser carried by the extensible finger (terminal end of catheter 20) to operate at a controlled rate (Col. 4, lines 18-30). Labbe et al also disclose a processor (66), software (Fig. 4; Col. 4, lines 3-18), that the device is configured for full placement in vivo, in a human animal, in a location corresponding to one physiological variable that needs to be treated (Col. 2, lines 55-60). Furthermore, Labbe et al disclose that the device provides a treatment to the patient comprising a medical agent (Col. 2, lines 56-58), and that the device communicates exterior to the patient (Col. 2, lines 59-60).

9. Claims 1, 10-14, 18, 19, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by USPN 6,296,638 B1 to Davison et al.

Regarding the above claims, Davison et al disclose a device comprising a body portion (10); at least one extensible finger (42) coupled to said body portion; at least one reservoir (32) in communication with said extensible finger; and a control circuitry (Col. 17, lines 40-49) coupled to said body portion. Davison et al further disclose an

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operative tool in communication with the extensible finger (102, 103, 104), as well as a tool positioner (handle 204). Davison et al also disclose that the operative tool is a device for ablation (Col. 19, lines 7-9), that the control circuitry guides (provides complete control over) the tool (Col. 17, lines 40-42), and a source of electric charge (10). Davison et al also disclose a device for evacuating a target or cauterizing (102, 103, 104), and that the control circuitry is coupled to guide or control the extensible finger (10).

10. Claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by USPN 6,086,528 to Adair.

Regarding the above claims, Adair discloses a body (handle), an extending part (probe), at least one receiving body (syringe) and a control circuit. The system also teaches use in stent delivery (Col. 2, lines 25-30).

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:



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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 9 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al.

Lebel et al teach the device of claims 1 and 30 as described above, but fail to teach that the delivered compound is a combination of two or more substances, or that the device is implanted in the vasculature. However, combination of drugs or substances for delivery is known in the drug delivery art, as is placement of the delivery device in the blood stream. Therefore, both of these limitations would have been obvious to one having ordinary skill in the art at the time the invention was made.

14. Claims 9 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Labbe et al.

Labbe et al teach the device of claims 1 and 30 as described above, but fail to teach that the delivered compound is a combination of two or more substances, or that the device is implanted in the vasculature. However, combination of drugs or substances for delivery is known in the drug delivery art, as is placement of the delivery device in the blood stream. Therefore, both of these limitations would have been obvious to one having ordinary skill in the art at the time the invention was made.

15. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al or Labbe et al in view of USPGPub 2002/0156462 A1 to Stultz.

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Regarding the above claims, Lebel et al and Labbe et al both teach the device of claim 1 as disclosed above, but fail to teach or disclose that the extensible finger includes a plurality of telescoping segments. However, Stultz discloses a series of hollow telescoping segments in Figure 3A which comprise the extensible finger 14'. At the time of invention, it would have been obvious to one having ordinary skill in the art to use a telescoping extensible finger such as that disclosed by Stultz because doing so would be a simple substitution of one known element (a non-telescoping catheter) for another (a telescoping catheter) in order to achieve a predictable result (drug delivery).

### ***Double Patenting***

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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17. Claims 1-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No. 10/827,576 and claims 1-41 of copending Application No. 10/827,390. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims a body, an extendable finger, at least one reservoir and a control circuit. Application 10/827,576 claims at least one arm (extendable finger), a control circuit, at least one receptacle (reservoir). Application 10/827,576 does not recite a body; however, this limitation would be obvious in that the incorporation of a housing is obvious. Application 10/827,390 claims a body, an extending part (extendable finger), a receiving body (reservoir) and a control circuit.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

18. Applicant's arguments with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection. The examiner draws applicant's attention to the more detailed rejections above for discussion on how each of the above references does indeed set forth all the limitations of the claimed invention

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell  
Examiner, AU 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763